K042793

OCT 29 2004

510(k) Summary
for the
Arcadis Orbic

Submitted by:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

October 01, 2004

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:
   Ms. Debbie Peacock
   51 Valley Stream Parkway E-50
   Malvern, PA 19355
   Phone: (610) 448-1773
   Fax: (610) 448-1787

2. Device Name and Classification:
   Trade Name: Arcadis Orbic
   Classification Name: Mobile X-Ray System
   Classification Panel: Radiology
   CFR Section: 21 CFR §892.1720
   Device Classification: Class II
   Product Code: OWB, OXO, JAA

3. Substantial Equivalence:
The Arcadis Orbic is substantially equivalent to the following devices:

Predicate Device Name	510(k) Number	Clearance Date	Comparable Properties
Siemens SIREMOBIL ISO-C (Cleared as the SIREMOBIL CO2)	K973598	11/10/1997	Hardware Control Software Intended use
Siemens SIREMOBIL ISO-C 3D	K040347	03/09/2004	Hardware Control Software Intended use

3D Navigation Interface for SIREMOBIL ISO-C 3D	K022337	08/13/2002	Hardware Control Software Intended use
Siemens Arcadis Varic (Cleared as the SIREMOBIL CO6)	K040066	02/12/2004	Hardware Control Software

4. Device Description:

The Arcadis Orbic is a mobile x-ray system which consists of a mobile C-arm configured with a high frequency generator, X-ray tube assembly, image intensifier, CCD camera, laser target devices, electronics cabinet, a monitor trolley and digital image storage system which consists of the digital memory device, image monitors, and user interface. The system is equipped with a footswitch and a hand switch for radiation release in the five modes of operation: digital radiography, fluoroscopy, pulsed fluoroscopy, subtraction, and roadmapping.

Intended Use of the Device:
The Arcadis Orbic is a mobile x-ray system designed to provide fluoroscopic and digital spot-film imaging of the patient during surgical and interventional procedures. Clinical applications may include, but are not limited to, cholangiography, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

The Arcadis Orbic 3D option provides 3D imaging and is intended to be used whenever the physician benefits from intraoperatively-generated 3D information of high contrast objects and anatomical structures.

The 3D Navigation Interface option provides visual support for planning and positioning of instruments during surgical procedures.

Summary of Technological Characteristics of the Devices Compared to the Predicate:

The Arcadis Orbic is a modification to the SIREMOBIL ISO-C (K973598, cleared by CDRH as the SIREMOBIL C02 on November 10, 1997). Mechanically the changes are minor in design and style. The X-ray generator, X-ray tube and Image Intensifier are identical with the currently cleared product.

The 3D imaging option is similar to the SIREMOBIL ISO-C 3D (K040347 cleared by CDRH on March 9, 2004).

The 3D navigation interface is similar to the 3D Navigation Interface (Navilink) software for the SIREMOBIL ISO C (K022337, cleared by CDRH on August 13, 2002).

The imaging chain reflects the current standard of 1024^2 image processing and display with flat screen monitors originally cleared with the Arcadis Varic and in clinical operation for

more than 10 months. An uninterruptable power supply provides additional safety to image and demographic data in the event of a power outage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ms. Debbie Peacock
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway E-50
MALVERN PA 19355

MAY 22 2012

Re: K042793
Trade/Device Name: ARCADIS ORBIC
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, and JAA
Dated: October 4, 2004
Received: October 7, 2004

Dear Ms. Peacock:

This letter corrects our substantially equivalent letter of November 14, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

The Arcadis Orbic is a mobile x-ray system designed to provide fluoroscopic and digital spot-film imaging of the patient during surgical and interventional procedures. Clinical applications may include, but are not limited to, cholangiography, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

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The 3D Navigation Interface option provides visual support for planning and positioning of instruments during surgical procedures.

510(k) Number (if known): K042793
Device Name: ARCADIS ORBIC

Indications For Use:

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042793